

Application No. 10/521,296
October 23, 2009

AMENDMENTS TO THE CLAIMS:

Claim 1 (Previously Presented). A stable pharmaceutical composition of erythropoietin (EPO), which consists essentially of:

- a. a therapeutically effective amount of EPO,
- b. a pharmaceutically acceptable pH buffering system,
- c. polyvinylpyrrolidone (PVP),
- d. optionally, an isotonifying agent,
- e. optionally, one or more pharmaceutically acceptable excipient(s) selected from the group consisting of polyols, hydroxypropylcellulose, methylcellulose, macrogol esters and ethers, glycol and glycerol esters, and amino acids, and
- f. optionally, a poloxamer as an additional stabilizer.

Claim 2 (Previously Presented). The composition according to claim 1, which is free of serum proteins, other than EPO, derived from human and/or animal origin.

Claim 3 (Previously Presented). The composition of claim 1, wherein the composition is aqueous.

Claim 4 (Previously Presented). The composition of claim 1, wherein the pharmaceutical quantity of EPO is formulated to provide a quantity per dose in the range of about 500 to about 100000 IU EPO.

Claim 5 (Original). The composition of claim 4, wherein the pharmaceutical quantity is formulated to provide a quantity per dose selected from the group consisting of about 1000 IU, about 2000 IU, about 3000 IU, about 4000 IU, about 10000 IU, about 20000 IU, about 25000 IU and about 40000 IU.

Claim 6 (Previously Presented). The composition of claim 1, wherein the pH buffering system provides a pH range from about 6 to about 8.

Claim 7 (Original). The composition of claim 6, wherein the pH buffering system provides a pH range from about 6.8 to about 7.5.

Claim 8 (Original). The composition of claim 6, wherein the pH buffering system provides a pH of about 7.0.

Claim 9 (Previously Presented). The composition of claim 1, wherein the pH buffering system is phosphate buffer.

Claim 10 (Previously Presented). The composition of claim 1, wherein PVP is comprised in a range of about 0.01% to about 1%.

Claim 11 (Original). The composition of claim 10, wherein PVP is comprised in a range of about 0.1% to about 1%.

Claim 12 (Original). The composition of claim 10, wherein the concentration of PVP is about 0.5%.

Claim 13 (Previously Presented). The composition of claim 1, wherein said PVP has a K value in a range from K12 to K18.

Claim 14 (Withdrawn). The composition of claim 1, wherein said isotonifying agent is selected from the group consisting of inorganic salts.

Claim 15 (Withdrawn). The composition of claim 14, wherein said isotonifying agent is NaCl.

Claims 16 – 18 (Cancelled).

Claim 19 (Currently Amended). A stable pharmaceutical composition of erythropoietin (EPO), which ~~consists of~~ comprises:

- a. a therapeutically effective amount of EPO,
- b. a pharmaceutically acceptable pH buffering system,
- c. an EPO stabilizer which consists of polyvinylpyrrolidone (PVP) and optionally a poloxamer,
- d. optionally, an isotonifying agent, and
- e. optionally, one or more pharmaceutically acceptable excipient(s) selected from the group consisting of polyols, hydroxypropylcellulose, methylcellulose, macrogol esters and ethers, glycol and glycerol esters, and amino acids, and
- f. optionally, a poloxamer as an additional stabilizer.

Claim 20 (Previously Presented) A stable aqueous solution of erythropoietin (EPO) comprising:

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erythropoietin (EPO), and
polyvinylpyrrolidone (PVP),

wherein the polyvinylpyrrolidone (PVP) is the sole stabilizer for the stabilization of the erythropoietin (EPO).

Claim 21 (Withdrawn). A method for the treatment of diseases indicated for erythropoietin (EPO), the method comprising administering a medicament comprising an effective amount of the composition of claim 1 to a patient in need thereof.